

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

NICOLE SOLTYKA, individually and
As personal representative of the *Estate of*
Anthony Soltyka
7007 Universal Court
Rockville, MD 20855

Case No.:

- AND -

TO THE USE OF FELICIA SOLTYKA
292 Main St
East Aurora, NY 14052

Plaintiffs,

v.

MONSANTO COMPANY
800 Lindbergh Boulevard
St. Louis County, Missouri

Serve:
CSC-LAWYERS INCORPORATING
SERVICE COMPANY
7 ST. PAUL STREET
SUITE 820
BALTIMORE MD 21202

Defendant.

COMPLAINT

COMES NOW, Plaintiff Nicole Soltyka, individually and as personal representative of the Estate of Anthony Soltyka, and to the use of Felicia Soltyka and states the following:

INTRODUCTION

Plaintiff brings this cause of action against Defendant. All claims in this action are a direct and proximate result of Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, and/or sale

of the products as Roundup®. Plaintiff seeks recovery for damages as a result of Anthony Soltyka (the decedent) developing Non-Hodgkin's Lymphoma ("NHL"), which was directly and proximately caused by such wrongful conduct by Defendant, the unreasonably dangerous and defective nature of Roundup®, and its active ingredient, glyphosate, and the attendant effects of developing NHL. Plaintiff did not know of an association between exposure to Roundup® and the increased risk of developing NHL until well after July 29, 2015, when the International Agency for Research on Cancer ("IARC"), an agency of the World Health Organization ("WHO"), first published its evaluation of glyphosate.

Plaintiff Nicole Soltyka brings each of her causes of action below individually pursuant to the Maryland Wrongful Death Act, Md. Code, Cts. & Jud. Proc. § 3-901, *et seq.*, and as personal representative for the estate of decedent Anthony Soltyka, pursuant to the Maryland Survival Act, Md. Code, Cts. & Jud. Proc. § 6-401

THE PARTIES

PLAINTIFF AND DECEDENT

1. Plaintiff Nicole Soltyka is a citizen of State of Maryland and the personal representative of the Estate of her deceased husband Anthony Soltyka. She brings this action as the surviving spouse, and personal and legal representative of Mr. Soltyka.

2. Decedent Anthony Soltyka was a citizen of the State of Maryland and is survived by his wife Nicole and mother Felecia.

3. Felecia Soltyka is the mother of the decedent and, upon information and believe a citizen of the State of New York. Ms. Felecia Soltyka is a "Use Plaintiff" pursuant to Md. Rule Civ. Proc. 15-1001.

4. Decedent was first exposed to Roundup® in as early as 2010. He sprayed Roundup® on his property on routine basis.

5. In 2014, Anthony Soltyka was diagnosed with (Non-Hodkins Lymphoma) in and suffered the effects attendant thereto ultimately succumbing to NHL and the sequelae of NHL and the corresponding treatment on August 22, 2019, as a direct and proximate result of the unreasonably dangerous and defective nature of Roundup® and Defendant's wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of Roundup®.

6. As a direct and proximate result of these injuries, Plaintiff has incurred medical expenses and has endured and will endure pain and suffering and loss of enjoyment of life, and Plaintiff has otherwise been damaged in a personal and pecuniary nature.

7. During the entire time that Decedent was exposed to Roundup®, he did not know that exposure to Roundup® was injurious to his health or the health of others.

DEFENDANT

8. Defendant Monsanto is a Delaware corporation with its headquarters and principal place of business in St. Louis, Missouri. At all relevant times, Monsanto also regularly conducted, transacted, and solicited business in the State of Maryland. Monsanto's world headquarters are located at 800 Lindbergh Boulevard in St. Louis County, Missouri.

9. At all times relevant to this complaint, Monsanto was the entity that discovered the herbicidal properties of glyphosate and the manufacturer of Roundup®, which contains the active ingredient glyphosate and the surfactant POEA, as well as adjuvants and other "inert" ingredients. On information and belief, important scientific, manufacturing, marketing, sales, and other business decisions regarding Roundup® were made from and in the State of Missouri.

10. At all times relevant to this complaint, Monsanto was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing Roundup® in the State of Missouri.

11. At all relevant times, Monsanto had, and continues to have, regular and systematic contact with and conducts business in and from the State of Maryland, such that it has purposefully availed itself of the laws of the Maryland and expects to both sue and be sued in Maryland. In the alternative, Monsanto's presence in the State of Maryland satisfies the due process requirements for Maryland courts to exercise jurisdiction over it.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 as the parties are completely diverse from each other and the amount in controversy exceeds \$75,000.00.

13. This Court has personal jurisdiction over each Defendant pursuant to Md. Code Ann., Cts. & Jud. Proc. § 6-102 and 6-103.

14. Venue lies in Montgomery County, Maryland as the cause of action arose therein.

ALLEGATIONS COMMON TO ALL COUNTS

15. In 1970, Defendant Monsanto Company, Inc. ("Monsanto") discovered the herbicidal properties of glyphosate and began marketing it in products in 1974 under the brand name Roundup®. Roundup® is a non-selective herbicide used to kill weeds that commonly compete with the growing of crops. In addition to the active ingredient glyphosate, Roundup® contains the surfactant Polyethoxylated tallow amine (POEA) and/or adjuvants and other so-called "inert" ingredients. In 2001, glyphosate was the most-used pesticide active ingredient in American agriculture with 85–90 million pounds used annually. That number grew to 185 million pounds in 2007.¹ As of 2013, glyphosate was the world's most widely used herbicide.

16. Monsanto is a multinational agricultural biotechnology corporation based in St. Louis, Missouri, and incorporated in Delaware. It is the world's leading producer of glyphosate. As

¹ Arthur Grube et al., U.S. Env'tl. Prot. Agency, *Pesticides Industry Sales and Usage, 2006–2007 Market Estimates* 14 (2011), available at http://www.epa.gov/pesticides/pestsales/07pestsales/market_estimates2007.pdf.

of 2009, Monsanto was the world's leading producer of seeds, accounting for 27% of the world seed market.² The majority of these seeds are of the Roundup Ready® brand. The stated advantage of Roundup Ready® crops is that they substantially improve a farmer's ability to control weeds, because glyphosate can be sprayed in the fields during the growing season without harming the crops. In 2010, an estimated 70% of corn and cotton and 90% of soybean fields in the United States were Roundup Ready®.³

17. Monsanto's glyphosate products are registered in 130 countries and approved for use on over 100 different crops.⁴ They are ubiquitous in the environment. Numerous studies confirm that glyphosate is found in rivers, streams, and groundwater in agricultural areas where Roundup® is used.⁵ It has been found in food,⁶ in the urine of agricultural workers,⁷ and even in the urine of urban dwellers who are not in direct contact with glyphosate.⁸

18. On March 20, 2015, the International Agency for Research on Cancer ("IARC"), an agency of the World Health Organization ("WHO"), issued an evaluation of several herbicides,

² ETC Group, *Who Will Control the Green Economy?* 22 (2011), available at http://www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf.

³ William Neuman & Andrew Pollack, *Farmers Cope With Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, available at <http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewanted=all>.

⁴ Monsanto, *Background-History of Monsanto's Glyphosate Herbicides* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf.

⁵ See U.S. Geological Survey, *USGS Technical Announcement: Widely Used Herbicide Commonly Found in Rain and Streams in the Mississippi River Basin* (2011), available at <http://www.usgs.gov/newsroom/article.asp?ID=2909>; see also U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate*, available at <http://www.epa.gov/safewater/pdfs/factsheets/soc/tech/glyphosa.pdf>.

⁶ Thomas Bohn et al., *Compositional Differences in Soybeans on the Market: Glyphosate Accumulates in Roundup Ready GM Soybeans*, 153 FOOD CHEMISTRY 207 (2013), available at <http://www.sciencedirect.com/science/article/pii/S0308814613019201>.

⁷ John F. Acquavella et al., *Glyphosate Biomonitoring for Farmers and Their Families: Results from the Farm Family Exposure Study*, 112(3) ENVTL. HEALTH PERSPECTIVES 321 (2004), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241861/>; Kathryn Z. Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, 112 IARC Monographs 76, section 5.4 (2015), available at [http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8).

⁸ Dirk Brändli & Sandra Reinacher, *Herbicides found in Human Urine*, 1 ITHAKA JOURNAL 270 (2012), available at <http://www.ithaka-journal.net/druckversionen/e052012-herbicides-urine.pdf>.

including glyphosate. That evaluation was based, in part, on studies of exposures to glyphosate in several countries around the world, and it traces the health implications from exposure to glyphosate since 2001.

19. On July 29, 2015, IARC issued the formal monograph relating to glyphosate. In that monograph, the IARC Working Group provides a thorough review of the numerous studies and data relating to glyphosate exposure in humans.

20. The IARC Working Group classified glyphosate as a Group 2A herbicide, which means that it is *probably carcinogenic to humans*. The IARC Working Group concluded that the cancers most associated with glyphosate exposure are NHL and other haematopoietic cancers, including lymphocytic lymphoma / chronic lymphocytic leukemia, B-cell lymphoma, and multiple myeloma.⁹

21. The IARC evaluation is significant. It confirms what has been believed for years: that glyphosate is toxic to humans.

22. Nevertheless, Monsanto, since it began selling Roundup®, has represented it as safe to humans and the environment. Indeed, Monsanto has repeatedly proclaimed and continues to proclaim to the world, and particularly to United States consumers, that glyphosate-based herbicides, including Roundup®, create no unreasonable risks to human health or to the environment.

FACTS

23. Glyphosate is a broad-spectrum, non-selective herbicide used in a wide variety of herbicidal products around the world.

24. Plants treated with glyphosate translocate the systemic herbicide to their roots, shoot regions, and fruit, where it interferes with the plant's ability to form aromatic amino acids necessary for protein synthesis. Treated plants generally die within two to three days. Because plants absorb

⁹ See Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, *supra*.

glyphosate, it cannot be completely removed by washing or peeling produce or by milling, baking, or brewing grains.

25. For nearly 40 years, farms across the world have used Roundup[®] without knowing of the dangers its use poses. That is because when Monsanto first introduced Roundup[®], it touted glyphosate as a technological breakthrough: it could kill almost every weed without causing harm either to people or to the environment. Of course, history has shown that not to be true. According to the WHO, the main chemical ingredient of Roundup[®]—glyphosate—is a probable cause of cancer. Those most at risk are farm workers and other individuals with workplace exposure to Roundup[®], such as garden center workers, nursery workers, and landscapers. Agricultural workers are, once again, victims of corporate greed. Monsanto assured the public that Roundup[®] was harmless. In order to prove this, Monsanto has championed falsified data and has attacked legitimate studies that revealed the dangers of Roundup[®]. Monsanto has led a prolonged campaign of misinformation to convince government agencies, farmers and the general population that Roundup[®] is safe.

The Discovery of Glyphosate and Development of Roundup[®]

26. The herbicidal properties of glyphosate were discovered in 1970 by Monsanto chemist John Franz. The first glyphosate-based herbicide was introduced to the market in the mid-1970s under the brand name Roundup[®].¹⁰ From the outset, Monsanto marketed Roundup[®] as a “safe” general-purpose herbicide for widespread commercial and consumer use. It still markets Roundup[®] as safe today.¹¹

¹⁰ Monsanto, *Background, History of Monsanto's Glyphosate Herbicide* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf.

¹¹ Monsanto, *What is Glyphosate?* (Sep. 2, 2015), <http://www.monsanto.com/sitecollectiondocuments/glyphosate-safety-health.pdf>.

27. In addition to the active ingredient glyphosate, Roundup[®] formulations also contain adjuvants and other chemicals, such as the surfactant POEA, which are considered “inert” and therefore protected as “trade secrets” in manufacturing. Growing evidence suggests that these adjuvants and additional components of Roundup[®] formulations are not, in fact, inert and are toxic in their own right.

Registration of Herbicides under Federal Law

28. The manufacture, formulation, and distribution of herbicides, such as Roundup[®], are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA” or “Act”), 7 U.S.C. § 136 *et seq.* FIFRA requires that all pesticides be registered with the Environmental Protection Agency (“EPA” or “Agency”) prior to their distribution, sale, or use, except as described by the Act. 7 U.S.C. § 136a(a).

29. Because pesticides are toxic to plants, animals, and humans, at least to some degree, the EPA requires as part of the registration process, among other things, a variety of tests to evaluate the potential for exposure to pesticides, toxicity to people and other potential non-target organisms, and other adverse effects on the environment. Registration by the EPA, however, is not an assurance or finding of safety. The determination the Agency must make in registering or re-registering a product is not that the product is “safe,” but rather that use of the product in accordance with its label directions “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(D).

30. FIFRA defines “unreasonable adverse effects on the environment” to mean “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” 7 U.S.C. § 136(bb). FIFRA thus requires EPA to make a risk/benefit analysis in determining whether a registration should be granted or a pesticide allowed to continue to be sold in commerce.

31. The EPA and the State of California registered Roundup® for distribution, sale, and manufacture in the United States.

32. FIFRA generally requires that the registrant, Monsanto in the case of Roundup®, conducts the health and safety testing of pesticide products. The EPA has protocols governing the conduct of tests required for registration and the laboratory practices that must be followed in conducting these tests. The data produced by the registrant must be submitted to the EPA for review and evaluation. The government is not required, nor is it able, however, to perform the product tests that are required of the manufacturer.

33. The evaluation of each pesticide product distributed, sold, or manufactured is completed at the time the product is initially registered. The data necessary for registration of a pesticide has changed over time. The EPA is now in the process of re-evaluating all pesticide products through a Congressionally-mandated process called “re-registration.” 7 U.S.C. § 136a-1. In order to re-evaluate these pesticides, the EPA is demanding the completion of additional tests and the submission of data for the EPA’s recent review and evaluation.

34. In the case of glyphosate, and therefore Roundup®, the EPA had planned on releasing its preliminary risk assessment—in relation to the reregistration process—no later than July 2015. The EPA completed its review of glyphosate in early 2015, but it delayed releasing the risk assessment pending further review in light of the WHO’s health-related findings.

Scientific Fraud Underlying the Marketing and Sale of Glyphosate/Roundup®

35. Based on early studies showing that glyphosate could cause cancer in laboratory animals, the EPA originally classified glyphosate as *possibly carcinogenic to humans* (Group C) in 1985. After pressure from Monsanto, including contrary studies it provided to the EPA, the EPA changed its classification to *evidence of non-carcinogenicity in humans* (Group E) in 1991. In so classifying glyphosate, however, the EPA made clear that the designation did not mean the chemical does not

cause cancer: “It should be emphasized, however, that designation of an agent in Group E is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.”¹²

36. On two occasions, the EPA found that the laboratories hired by Monsanto to test the toxicity of its Roundup[®] products for registration purposes committed fraud.

37. In the first instance, Monsanto, in seeking initial registration of Roundup[®] by the EPA, hired Industrial Bio-Test Laboratories (“IBT”) to perform and evaluate pesticide toxicology studies relating to Roundup[®].¹³ IBT performed about 30 tests on glyphosate and glyphosate-containing products, including nine of the 15 residue studies needed to register Roundup[®].

38. In 1976, the United States Food and Drug Administration (“FDA”) performed an inspection of IBT that revealed discrepancies between the raw data and the final report relating to the toxicological impacts of glyphosate. The EPA subsequently audited IBT; it too found the toxicology studies conducted for the Roundup[®] herbicide to be invalid.¹⁴ An EPA reviewer stated, after finding “routine falsification of data” at IBT, that it was “hard to believe the scientific integrity of the studies when they said they took specimens of the uterus from male rabbits.”¹⁵

¹² U.S. Env'tl. Prot. Agency, *Memorandum, Subject: SECOND Peer Review of Glyphosate 1* (1991), available at http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-Oct-91_265.pdf.

¹³ Monsanto, *Background, Testing Fraud: IBT and Craven Laboratories* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt_craven_bkg.pdf.

¹⁴ U.S. Env'tl. Prot. Agency, *Summary of the IBT Review Program Office of Pesticide Programs* (1983), available at <http://nepis.epa.gov/Exe/ZyNET.exe/91014ULV.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1981+Thru+1985&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C81thru85%5CTxt%5C00000022%5C91014ULV.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL>.

¹⁵ Marie-Monique Robin, *The World According to Monsanto: Pollution, Corruption and the Control of the World's Food Supply* (2011) (citing U.S. Env'tl. Prot. Agency, *Data Validation, Memo from K. Locke, Toxicology Branch, to R. Taylor, Registration Branch, Washington, D.C. (August 9, 1978)*).

39. Three top executives of IBT were convicted of fraud in 1983.

40. In the second incident of data falsification, Monsanto hired Craven Laboratories in 1991 to perform pesticide and herbicide studies, including for Roundup[®]. In that same year, the owner of Craven Laboratories and three of its employees were indicted, and later convicted, of fraudulent laboratory practices in the testing of pesticides and herbicides.¹⁶

41. Despite the falsity of the tests that underlie its registration, within a few years of its launch, Monsanto was marketing Roundup[®] in 115 countries.

The Importance of Roundup[®] to Monsanto's Market Dominance Profits

42. The success of Roundup[®] was key to Monsanto's continued reputation and dominance in the marketplace. Largely due to the success of Roundup[®] sales, Monsanto's agriculture division was out-performing its chemicals division's operating income, and that gap increased yearly. But with its patent for glyphosate expiring in the United States in the year 2000, Monsanto needed a strategy to maintain its Roundup[®] market dominance and to ward off impending competition.

43. In response, Monsanto began the development and sale of genetically engineered Roundup Ready[®] seeds in 1996. Since Roundup Ready[®] crops are resistant to glyphosate, farmers can spray Roundup[®] onto their fields during the growing season without harming the crop. This allowed Monsanto to expand its market for Roundup[®] even further; by 2000, Monsanto's biotechnology seeds were planted on more than 80 million acres worldwide and nearly 70% of American soybeans were planted from Roundup Ready[®] seeds. It also secured Monsanto's dominant share of the glyphosate/Roundup[®] market through a marketing strategy that coupled proprietary Roundup Ready[®] seeds with continued sales of its Roundup[®] herbicide.

¹⁶ Monsanto, *Background, Testing Fraud: IBT and Craven Laboratories*, *supra*.

44. Through a three-pronged strategy of increasing production, decreasing prices, and by coupling with Roundup Ready® seeds, Roundup® became Monsanto's most profitable product. In 2000, Roundup® accounted for almost \$2.8 billion in sales, outselling other herbicides by a margin of five to one, and accounting for close to half of Monsanto's revenue.¹⁷ Today, glyphosate remains one of the world's largest herbicides by sales volume.

Monsanto has known for decades that it falsely advertises the safety of Roundup®

45. In 1996, the New York Attorney General ("NYAG") filed a lawsuit against Monsanto based on its false and misleading advertising of Roundup® products. Specifically, the lawsuit challenged Monsanto's general representations that its spray-on glyphosate-based herbicides, including Roundup®, were "**safer than table salt**" and "**practically non-toxic**" to mammals, birds, and fish. Among the representations the NYAG found deceptive and misleading about the human and environmental safety of glyphosate and/or Roundup® are the following:

a) "Remember that environmentally friendly Roundup herbicide is biodegradable. It won't build up in the soil so you can use Roundup with confidence along customers' driveways, sidewalks and fences ..."

b) "And remember that Roundup is biodegradable and won't build up in the soil. That will give you the environmental confidence you need to use Roundup everywhere you've got a weed, brush, edging or trimming problem."

c) "Roundup biodegrades into naturally occurring elements."

d) "Remember that versatile Roundup herbicide stays where you put it. That means there's no washing or leaching to harm customers' shrubs or other desirable vegetation."

e) "This non-residual herbicide will not wash or leach in the soil. It ... stays where you apply it."

¹⁷ David Barboza, *The Power of Roundup: A Weed Killer Is A Block for Monsanto to Build On*, N.Y. TIMES, Aug. 2, 2001, available at <http://www.nytimes.com/2001/08/02/business/the-power-of-roundup-a-weed-killer-is-a-block-for-monsanto-to-build-on.html>.

f) “You can apply Accord with ‘confidence because it will stay where you put it’ it bonds tightly to soil particles, preventing leaching. Then, soon after application, soil microorganisms biodegrade Accord into natural products.”

g) “Glyphosate is less toxic to rats than table salt following acute oral ingestion.”

h) “Glyphosate’s safety margin is much greater than required. It has over a 1,000-fold safety margin in food and over a 700-fold safety margin for workers who manufacture it or use it.”

i) “You can feel good about using herbicides by Monsanto. They carry a toxicity category rating of ‘practically non-toxic’ as it pertains to mammals, birds and fish.”

j) “Roundup can be used where kids and pets will play and breaks down into natural material.” This ad depicts a person with his head in the ground and a pet dog standing in an area which has been treated with Roundup.¹⁸

46. On November 19, 1996, Monsanto entered into an Assurance of Discontinuance with NYAG, in which Monsanto agreed, among other things, “to cease and desist from publishing or broadcasting any advertisements [in New York] that represent, directly or by implication” that:

a) its glyphosate-containing pesticide products or any component thereof are safe, non-toxic, harmless or free from risk.

* * *

b) its glyphosate-containing pesticide products or any component thereof manufactured, formulated, distributed or sold by Monsanto are biodegradable

* * *

c) its glyphosate-containing pesticide products or any component thereof stay where they are applied under all circumstances and will not move through the environment by any means.

* * *

¹⁸ Attorney General of the State of New York, In the Matter of Monsanto Company, Assurance of Discontinuance Pursuant to Executive Law § 63(15) (Nov. 1996).

d) its glyphosate-containing pesticide products or any component thereof are “good” for the environment or are “known for their environmental characteristics.”

* * *

e) glyphosate-containing pesticide products or any component thereof are safer or less toxic than common consumer products other than herbicides;

f) its glyphosate-containing products or any component thereof might be classified as “practically non-toxic.”

47. Monsanto did not alter its advertising in the same manner in any state other than New York, and on information and belief it still has not done so today.

48. In 2009, France’s highest court ruled that Monsanto had not told the truth about the safety of Roundup®. The French court affirmed an earlier judgement that Monsanto had falsely advertised its herbicide Roundup® as “biodegradable” and that it “left the soil clean.”¹⁹

Classifications and Assessments of Glyphosate

49. The IARC process for the classification of glyphosate followed IARC’s stringent procedures for the evaluation of a chemical agent. Over time, the IARC Monograph program has reviewed 980 agents. Of those reviewed, it has determined 116 agents to be Group 1 (Known Human Carcinogens); 73 agents to be Group 2A (Probable Human Carcinogens); 287 agents to be Group 2B (Possible Human Carcinogens); 503 agents to be Group 3 (Not Classified); and one agent to be Probably Not Carcinogenic.

¹⁹ *Monsanto Guilty in ‘False Ad’ Row*, BBC, Oct. 15, 2009, available at <http://news.bbc.co.uk/2/hi/europe/8308903.stm>.

50. The established procedure for IARC Monograph evaluations is described in the IARC Programme's Preamble.²⁰ Evaluations are performed by panels of international experts, selected on the basis of their expertise and the absence of actual or apparent conflicts of interest.

51. One year before the Monograph meeting, the meeting is announced and there is a call both for data and for experts. Eight months before the Monograph meeting, the Working Group membership is selected and the sections of the Monograph are developed by the Working Group members. One month prior to the Monograph meeting, the call for data is closed and the various draft sections are distributed among Working Group members for review and comment. Finally, at the Monograph meeting, the Working Group finalizes review of all literature, evaluates the evidence in each category, and completes the overall evaluation. Within two weeks after the Monograph meeting, the summary of the Working Group findings are published in *The Lancet Oncology*, and within a year after the meeting, the finalized Monograph is published.

52. In assessing an agent, the IARC Working Group reviews the following information: (a) human, experimental, and mechanistic data; (b) all pertinent epidemiological studies and cancer bioassays; and (c) representative mechanistic data. The studies must be publicly available and have sufficient detail for meaningful review, and reviewers cannot be associated with the underlying study.

53. In March 2015, IARC reassessed glyphosate. The summary published in *The Lancet Oncology* reported that glyphosate is a Group 2A agent and probably carcinogenic in humans.

54. On July 29, 2015, IARC issued its Monograph for glyphosate, Monograph Volume 112. For Volume 112, a Working Group of 17 experts from 11 countries met at IARC from March 3–10, 2015 to assess the carcinogenicity of certain herbicides, including glyphosate. The March meeting culminated a nearly one-year review and preparation by the IARC Secretariat and the

²⁰ World Health Org., *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble* (2006), available at <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

Working Group, including a comprehensive review of the latest available scientific evidence. According to published procedures, the Working Group considered “reports that have been published or accepted for publication in the openly available scientific literature” as well as “data from governmental reports that are publicly available.”

55. The studies considered the following exposure groups: (1) occupational exposure of farmers and tree nursery workers in the United States, forestry workers in Canada and Finland and municipal weed-control workers in the United Kingdom; and (2) para-occupational exposure in farming families.

56. Glyphosate was identified as the second-most used household herbicide in the United States for weed control between 2001 and 2007 and the most heavily used herbicide in the world in 2012.

57. Exposure pathways are identified as air (especially during spraying), water, and food. Community exposure to glyphosate is widespread and found in soil, air, surface water, and groundwater, as well as in food.

58. The assessment of the IARC Working Group identified several case control studies of occupational exposure in the United States, Canada, and Sweden. These studies show a human health concern from agricultural and other work-related exposure to glyphosate.

59. The IARC Working Group found an increased risk between exposure to glyphosate and NHL and several subtypes of NHL, and the increased risk persisted after adjustment for other pesticides.

60. The IARC Working Group also found that glyphosate caused DNA and chromosomal damage in human cells. One study in community residents reported increases in blood markers of chromosomal damage (micronuclei) after glyphosate formulations were sprayed.

61. In male CD-1 mice, glyphosate induced a positive trend in the incidence of a rare tumor: renal tubule carcinoma. A second study reported a positive trend for haemangiosarcoma in male mice. Glyphosate increased pancreatic islet-cell adenoma in male rats in two studies. A glyphosate formulation promoted skin tumors in an initiation-promotion study in mice.

62. The IARC Working Group also noted that glyphosate has been detected in the urine of agricultural workers, indicating absorption. Soil microbes degrade glyphosate to aminomethylphosphoric acid (AMPA). Blood AMPA detection after exposure suggests intestinal microbial metabolism in humans.

63. The IARC Working Group further found that glyphosate and glyphosate formulations induced DNA and chromosomal damage in mammals, and in human and animal cells in utero.

64. The IARC Working Group also noted genotoxic, hormonal, and enzymatic effects in mammals exposed to glyphosate.²¹ Essentially, glyphosate inhibits the biosynthesis of aromatic amino acids, which leads to several metabolic disturbances, including the inhibition of protein and secondary product biosynthesis and general metabolic disruption.

65. The IARC Working Group also reviewed an Agricultural Health Study, consisting of a prospective cohort of 57,311 licensed pesticide applicators in Iowa and North Carolina.²² While this study differed from others in that it was based on a self-administered questionnaire, the results support an association between glyphosate exposure and multiple myeloma, hairy cell leukemia (HCL), and chronic lymphocytic leukemia (CLL), in addition to several other cancers.

²¹ Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, *supra* at 77.

²² Anneclare J. De Roos et al., *Cancer Incidence Among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study*, 113 *Env'tl Health Perspectives* 49–54 (2005), *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1253709/pdf/ehp0113-000049.pdf>.

Other Earlier Findings About Glyphosate's Dangers to Human Health

66. The EPA has a technical fact sheet, as part of its Drinking Water and Health, National Primary Drinking Water Regulations publication, relating to glyphosate. This technical fact sheet predates IARC's March 20, 2015 evaluation. The fact sheet describes the release patterns for glyphosate as follows:

Release Patterns

Glyphosate is released to the environment in its use as a herbicide for controlling woody and herbaceous weeds on forestry, right-of-way, cropped and non-cropped sites. These sites may be around water and in wetlands.

It may also be released to the environment during its manufacture, formulation, transport, storage, disposal and cleanup, and from spills. Since glyphosate is not a listed chemical in the Toxics Release Inventory, data on releases during its manufacture and handling are not available.

Occupational workers and home gardeners may be exposed to glyphosate by inhalation and dermal contact during spraying, mixing, and cleanup. They may also be exposed by touching soil and plants to which glyphosate was applied. Occupational exposure may also occur during glyphosate's manufacture, transport storage, and disposal.²³

67. In 1995, the Northwest Coalition for Alternatives to Pesticides reported that in California, the state with the most comprehensive program for reporting of pesticide-caused illness, glyphosate was the third most commonly-reported cause of pesticide illness among agricultural workers.²⁴

The Toxicity of Other Ingredients in Roundup®

²³ U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate*, *supra*.

²⁴ Caroline Cox, *Glyphosate, Part 2: Human Exposure and Ecological Effects*, 15 J. PESTICIDE REFORM 4 (1995); W.S. Peas et al., *Preventing pesticide-related illness in California agriculture: Strategies and priorities*, *Environmental Health Policy Program Report*, Univ. of Cal. School of Public Health, Calif. Policy Seminar (1993).

68. In addition to the toxicity of the active ingredient, glyphosate, several studies support the hypothesis that the glyphosate-based formulation in Defendant's Roundup[®] products is more dangerous and toxic than glyphosate alone. Indeed, as early as 1991, available evidence demonstrated that glyphosate formulations were significantly more toxic than glyphosate alone.²⁵

69. In 2002, a study by Julie Marc, entitled "Pesticide Roundup Provokes Cell Division Dysfunction at the Level of CDK1/Cyclin B Activation," revealed that Roundup[®] causes delays in the cell cycles of sea urchins but that the same concentrations of glyphosate alone were ineffective and did not alter cell cycles.²⁶

70. A 2004 study by Marc and others, entitled "Glyphosate-based pesticides affect cell cycle regulation," demonstrated a molecular link between glyphosate-based products and cell cycle dysregulation. The researchers noted that "cell-cycle dysregulation is a hallmark of tumor cells and human cancer. Failure in the cell-cycle checkpoints leads genomic instability and subsequent development of cancers from the initial affected cell." Further, "[s]ince cell cycle disorders such as cancer result from dysfunction of a unique cell, it was of interest to evaluate the threshold dose of glyphosate affecting the cells."²⁷

71. In 2005, a study by Francisco Peixoto, entitled "Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation," demonstrated that Roundup[®]'s effects on rat liver mitochondria are far more toxic than equal concentrations of glyphosate alone. The Peixoto study further suggested that the harmful effects of Roundup[®] on mitochondrial bioenergetics could not be exclusively attributed to glyphosate but could be the result of other

²⁵ Martinez, T.T. and K. Brown, *Oral and pulmonary toxicology of the surfactant used in Roundup herbicide*, PROC. WEST. PHARMACOL. SOC. 34:43-46 (1991).

²⁶ Julie Marc, et al., *Pesticide Roundup Provokes Cell Division Dysfunction at the Level of CDK1/Cyclin B Activation*, 15 CHEM. RES. TOXICOL. 326-331 (2002), available at <http://pubs.acs.org/doi/full/10.1021/tx015543g>.

²⁷ Julie Marc, et al., *Glyphosate-based pesticides affect cell cycle regulation*, 96 BIOLOGY OF THE CELL 245, 245-249 (2004), available at <http://onlinelibrary.wiley.com/doi/10.1016/j.biocel.2003.11.010/epdf>.

chemicals, such as the surfactant POEA, or in the alternative, due to a potential synergic effect between glyphosate and other ingredients in the Roundup[®] formulation.²⁸

72. In 2009, Nora Benachour and Gilles-Eric Seralini published a study examining the effects of Roundup[®] and glyphosate on human umbilical, embryonic, and placental cells. The study tested dilution levels of Roundup[®] and glyphosate that were far below agricultural recommendations, corresponding with low levels of residue in food. The researchers ultimately concluded that supposed “inert” ingredients, and possibly POEA, alter human cell permeability and amplify toxicity of glyphosate alone. The researchers further suggested that assessments of glyphosate toxicity should account for the presence of adjuvants or additional chemicals used in the formulation of the complete pesticide. The study confirmed that the adjuvants present in Roundup[®] are not, in fact, inert and that Roundup[®] is potentially far more toxic than its active ingredient glyphosate alone.²⁹

73. The results of these studies were at all times available to Defendant. Defendant thus knew or should have known that Roundup[®] is more toxic than glyphosate alone and that safety studies of Roundup[®], Roundup’s adjuvants and “inert” ingredients, and/or the surfactant POEA were necessary to protect Plaintiff from Roundup[®].

74. Despite its knowledge that Roundup[®] is considerably more dangerous than glyphosate alone, Defendant continued to promote Roundup[®] as safe.

Recent Worldwide Bans on Roundup[®]/Glyphosate

75. Several countries around the world have instituted bans on the sale of Roundup[®] and other glyphosate-containing herbicides, both before and since IARC first announced its assessment

²⁸ Francisco Peixoto, *Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation*, 61 CHEMOSPHERE 1115, 1122 (2005), available at https://www.researchgate.net/publication/7504567_Comparative_effects_of_the_Roundup_and_glyphosate_on_mitochondrial_oxidative_phosphorylation.

²⁹ Nora Benachour, et al., *Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells*, 22 CHEM. RES. TOXICOL. 97-105 (2008), available at <http://big.assets.huffingtonpost.com/france.pdf>.

for glyphosate in March 2015, and more countries undoubtedly will follow suit as the dangers of the use of Roundup[®] become more widely known. The Netherlands issued a ban on all glyphosate-based herbicides in April 2014, including Roundup[®], which will take effect by the end of 2015. In issuing the ban, the Dutch Parliament member who introduced the successful legislation stated: “Agricultural pesticides in user-friendly packaging are sold in abundance to private persons. In garden centers, Roundup[®] is promoted as harmless, but unsuspecting customers have no idea what the risks of this product are. Especially children are sensitive to toxic substances and should therefore not be exposed to it.”³⁰

76. The Brazilian Public Prosecutor in the Federal District requested that the Brazilian Justice Department suspend the use of glyphosate.³¹

77. France banned the private sale of Roundup[®] and glyphosate following the IARC assessment for Glyphosate.³²

78. Bermuda banned both the private and commercial sale of glyphosates, including Roundup[®]. The Bermuda government explained its ban as follows: “Following a recent scientific study carried out by a leading cancer agency, the importation of weed spray ‘Roundup’ has been suspended.”³³

³⁰ *Holland’s Parliament Bans Glyphosate Herbicides*, The Real Agenda, April 14, 2014, available at <http://real-agenda.com/hollands-parliament-bans-glyphosate-herbicides/>.

³¹ Christina Sarich, *Brazil’s Public Prosecutor Wants to Ban Monsanto’s Chemicals Following Recent Glyphosate-Cancer Link*, GLOBAL RESEARCH, May 14, 2015, available at <http://www.globalresearch.ca/brazils-public-prosecutor-wants-to-ban-monsantos-chemicals-following-recent-glyphosate-cancer-link/5449440>; see Ministério Público Federal, *MPF/DF reforça pedido para que glifosato seja banido do mercado nacional*, April, 14, 2015, available at http://noticias.pgr.mpf.mp.br/noticias/noticias-do-site/copy_of_meio-ambiente-e-patrimonio-cultural/mpf-df-reforca-pedido-para-que-glifosato-seja-banido-do-mercado-nacional.

³² Zoe Schlanger, *France Bans Sales of Monsanto’s Roundup in Garden Centers, 3 Months After U.N. Calls it ‘Probable Carcinogen’*, NEWSWEEK, June 15, 2015, available at <http://www.newsweek.com/france-bans-sale-monsantos-roundup-garden-centers-after-un-names-it-probable-343311>.

³³ *Health Minister: Importation of Roundup Weed Spray Suspended*, Today in Bermuda, May, 11 2015, available at <http://www.todayinbermuda.com/news/health/item/1471-health-minister-importation-of-roundup-weed-spray-suspended>.

79. The Sri Lankan government banned the private and commercial use of glyphosate, particularly out of concern that glyphosate has been linked to fatal kidney disease in agricultural workers.³⁴

80. The government of Colombia announced its ban on using Roundup[®] and glyphosate to destroy illegal plantations of coca, the raw ingredient for cocaine, because of the WHO's finding that glyphosate is probably carcinogenic.³⁵

EFSA Report on Glyphosate

81. On November 12, 2015, the European Food Safety Authority (EFSA), the European Union's primary agency for food safety, reported on its evaluation of the Renewal Assessment Report (RAR) on glyphosate.³⁶ The Rapporteur Member State assigned to glyphosate, the German Federal Institute for Risk Assessment (BfR), had produced the RAR as part of the renewal process for glyphosate in the EU.

82. BfR sent its draft RAR to EFSA and the RAR underwent a peer review process by EFSA, other member states, and industry groups. As part of the on-going peer review of Germany's reevaluation of glyphosate, EFSA had also received a second mandate from the European Commission to consider IARC's findings regarding the potential carcinogenicity of glyphosate and glyphosate-containing products.

83. Based on a review of the RAR, which included data from industry-submitted unpublished studies, EFSA sent its own report ("Conclusion") to the European Commission,

³⁴ *Sri Lanka's New President Puts Immediate Ban on Glyphosate Herbicides*, Sustainable Pulse, May 25, 2015, available at <http://sustainablepulse.com/2015/05/25/sri-lankas-new-president-puts-immediate-ban-on-glyphosate-herbicides/#.VeduYk3bKAw>.

³⁵ *Columbia to ban coca spraying herbicide glyphosate*, BBC, May 10, 2015, available at <http://www.bbc.com/news/world-latin-america-32677411>.

³⁶ European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, available at http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf.

finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008.”³⁷ EFSA therefore disagreed with IARC: glyphosate was not genotoxic and did not present a carcinogenic threat to humans.

84. In explaining why its results departed from IARC’s conclusion, EFSA drew a distinction between the EU and IARC approaches to the study and classification of chemicals.³⁸ Although IARC examined “both glyphosate—an active substance—and glyphosate-based formulations, grouping all formulations regardless of their composition,” EFSA explained that it considered only glyphosate and that its assessment focuses on “each individual chemical, and each marketed mixture separately.”³⁹ IARC, on the other hand, “assesses generic agents, including groups of related chemicals, as well as occupational or environmental exposure, and cultural or behavioural practices.”⁴⁰ EFSA accorded greater weight to studies conducted with glyphosate alone than studies of formulated products.⁴¹

85. EFSA went further and noted:

[A]lthough some studies suggest that certain glyphosate-based formulations may be genotoxic (i.e. damaging to DNA), others that look solely at the active substance glyphosate do not show this effect. It is likely, therefore, that *the genotoxic effects observed in some glyphosate-based formulations are related to the other constituents or “co-formulants”*. Similarly, certain glyphosate-based formulations display higher toxicity than that of the active ingredient, presumably because of the presence of co-formulants. In its assessment, *EFSA proposes that the toxicity of each pesticide formulation and in particular its genotoxic potential should be further considered and*

³⁷ *Id.*

³⁸ EFSA Fact Sheet: Glyphosate, EFSA
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

*addressed by Member State authorities while they re-assess uses of glyphosate-based formulations in their own territories.*⁴²

86. Notwithstanding its conclusion, EFSA did set exposure levels for glyphosate. Specifically, EFSA proposed an acceptable daily intake (ADI) of 0.5 mg/kg of body weight per day; an acute reference dose (ARfD) of 0.5 mg/kg of body weight; and an acceptable operator exposure level (AOEL) of 0.1 mg/kg bw per day.⁴³

Leading Scientists Dispute EFSA's Conclusion

87. On November 27, 2015, 96 independent academic and governmental scientists from around the world submitted an open letter to the EU health commissioner, Vytenis Andriukaitis.⁴⁴ The scientists expressed their strong concerns and urged the commissioner to disregard the “flawed” EFSA report, arguing that “the BfR decision is not credible because it is not supported by the evidence and it was not reached in an open and transparent manner.”⁴⁵

88. Signatories to the letter included Dr. Christopher J. Portier, Ph.D., and other renowned international experts in the field, some of whom were part of the IARC Working Group assigned to glyphosate.

89. In an exhaustive and careful examination, the scientists scrutinized EFSA's conclusions and outlined why the IARC Working Group decision was “by far the more credible”:

The IARC WG decision was reached relying on open and transparent procedures by independent scientists who completed thorough conflict-of-interest statements and were not affiliated or financially supported in any way by the chemical manufacturing industry. It is fully referenced and depends entirely on reports published in the open,

⁴² *Id.*

⁴³ European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, *supra*.

⁴⁴ Letter from Christopher J. Portier et al. to Commission Vytenis Andriukaitis, Open letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR (Nov. 27, 2015), <http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf>; <http://www.theguardian.com/environment/2016/jan/13/eu-scientists-in-row-over-safety-of-glyphosate-weedkiller>.

⁴⁵ *Id.* <http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf>

peer-reviewed biomedical literature. It is part of a long tradition of deeply researched and highly credible reports on the carcinogenicity of hundreds of chemicals issued over the past four decades by IARC and used today by international agencies and regulatory bodies around the world as a basis for risk assessment, regulation and public health policy.⁴⁶

90. With respect to human data, the scientists pointed out that EFSA agreed with IARC that there was “*limited evidence* of carcinogenicity” for NHL, but EFSA nonetheless dismissed an association between glyphosate exposure and carcinogenicity. IARC applies three levels of evidence in its analyses of human data, including sufficient evidence and limited evidence. EFSA’s ultimate conclusion that “there was no unequivocal evidence for a clear and strong association of NHL with glyphosate” was misleading because it was tantamount to IARC’s highest level of evidence: “sufficient evidence,” which means that a causal relationship has been established. However, the scientists argued, “[l]egitimate public health concerns arise when ‘causality is credible,’ i.e., when there is *limited evidence*.”⁴⁷

91. Among its many other deficiencies, EFSA’s conclusions regarding animal carcinogenicity data were “scientifically unacceptable,” particularly in BfR’s use of historical control data and in its trend analysis. Indeed, BfR’s analysis directly contradicted the Organisation for Economic Co-operation and Development (“OECD”) testing guidelines while citing and purporting to follow those same guidelines. For instance, the EFSA report dismisses observed trends in tumor incidence “because there are no individual treatment groups that are significantly different from controls and because the maximum observed response is reportedly within the range of the historical control data.” However, according to the scientists, concurrent controls are recommended over historical controls in all guidelines, scientific reports, and publications, and, if it is employed,

⁴⁶ *Id.*

⁴⁷ *Id.*

historical control data “should be from studies in the same timeframe, for the same exact animal strain, preferably from the same laboratory or the same supplier and preferably reviewed by the same pathologist.” BfR’s use of historical control data violated these precautions: “only a single study used the same mouse strain as the historical controls, but was reported more than 10 years after the historical control dataset was developed.” Further deviating from sound scientific practices, the data used by the BfR came from studies in seven different laboratories. The scientists concluded:

BfR reported seven positive mouse studies with three studies showing increases in renal tumors, two with positive findings for hemangiosarcomas, and two with positive findings for malignant lymphomas. BfR additionally reported two positive findings for tumors in rats. Eliminating the inappropriate use of historical data, the unequivocal conclusion is that these are not negative studies, but in fact document the carcinogenicity of glyphosate in laboratory animals.⁴⁸

92. The letter also critiqued the EFSA report’s lack of transparency and the opacity surrounding the data cited in the report: “citations for almost all of the references, even those from the open scientific literature, have been redacted from the document” and “there are no authors or contributors listed for either document, a requirement for publication in virtually all scientific journals.” Because BfR relied on unpublished, confidential industry-provided studies, it is “impossible for any scientist not associated with BfR to review this conclusion with scientific confidence.”⁴⁹

93. On March 3, 2016, the letter was published in the *Journal of Epidemiology & Community Health*.⁵⁰

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ Christopher J. Portier, et al., *Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)*, JOURNAL OF EPIDEMIOLOGY & CMTY. HEALTH, Mar. 3, 2016, available at <http://jech.bmj.com/content/early/2016/03/03/jech-2015-207005.full>.

Statement of Concern Regarding Glyphosate-Based Herbicides

94. On February 17, 2016, a consensus statement published in the journal *Environmental Health*, entitled “Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement,” assessed the safety of glyphosate-based herbicides (GBHs).⁵¹ The paper’s “focus is on the unanticipated effects arising from the worldwide increase in use of GBHs, coupled with recent discoveries about the toxicity and human health risks stemming from use of GBHs.”⁵² The researchers drew seven factual conclusions about GBHs:

1. GBHs are the most heavily applied herbicide in the world and usage continues to rise;
2. Worldwide, GBHs often contaminate drinking water sources, precipitation, and air, especially in agricultural regions;
3. The half-life of glyphosate in water and soil is longer than previously recognized;
4. Glyphosate and its metabolites are widely present in the global soybean supply;
5. Human exposures to GBHs are rising;
6. Glyphosate is now authoritatively classified as a probable human carcinogen; and
7. Regulatory estimates of tolerable daily intakes for glyphosate in the United States and European Union are based on outdated science.⁵³

95. The researchers noted that GBH use has increased approximately 100-fold since the 1970s. Further, far from posing a limited hazard to vertebrates, as previously believed, two decades of evidence demonstrated that “several vertebrate pathways are likely targets of action, including

⁵¹ John P. Myers, et al, *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, *Environmental Health* (2016), available at <http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>.

⁵² *Id.*

⁵³ *Id.*

hepatorenal damage, effects on nutrient balance through glyphosate chelating action and endocrine disruption.”⁵⁴

96. The paper attributes uncertainties in current assessments of glyphosate formulations to the fact that “[t]he full list of chemicals in most commercial GBHs is protected as ‘commercial business information,’ despite the universally accepted relevance of such information to scientists hoping to conduct an accurate risk assessment of these herbicide formulations.” Further, the researchers argue, “[t]he distinction in regulatory review and decision processes between ‘active’ and ‘inert’ ingredients has no toxicological justification, given increasing evidence that several so-called ‘inert’ adjuvants are toxic in their own right.”⁵⁵

97. Among various implications, the researchers conclude that “existing toxicological data and risk assessments are not sufficient to infer that GBHs, as currently used, are safe.” Further, “GBH-product formulations are more potent, or toxic, than glyphosate alone to a wide array of non-target organisms including mammals, aquatic insects, and fish.” Accordingly, “risk assessments of GBHs that are based on studies quantifying the impacts of glyphosate alone underestimate both toxicity and exposure, and thus risk.” The paper concludes that this “shortcoming has repeatedly led regulators to set inappropriately high exposure thresholds.”⁵⁶

98. The researchers also critique the current practice of regulators who largely rely on “unpublished, non-peer reviewed data generated by the registrants” but ignore “published research because it often uses standards and procedures to assess quality that are different from those codified in regulatory agency data requirements, which largely focus on avoiding fraud.” In the researchers’

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

view, “[s]cientists independent of the registrants should conduct regulatory tests of GBHs that include glyphosate alone, as well as GBH-product formulations.”⁵⁷

99. The researchers also call for greater inclusion of GBHs in government-led toxicology testing programs:

[A] fresh and independent examination of GBH toxicity should be undertaken, and . . . this re-examination be accompanied by systematic efforts by relevant agencies to monitor GBH levels in people and in the food supply, none of which are occurring today. The U.S. National Toxicology Program should prioritize a thorough toxicological assessment of the multiple pathways now identified as potentially vulnerable to GBHs.⁵⁸

100. The researchers suggest that, in order to fill the gap created by an absence of government funds to support research on GBHs, regulators could adopt a system through which manufacturers fund the registration process and the necessary testing:

“[W]e recommend that a system be put in place through which manufacturers of GBHs provide funds to the appropriate regulatory body as part of routine registration actions and fees. Such funds should then be transferred to appropriate government research institutes, or to an agency experienced in the award of competitive grants. In either case, funds would be made available to independent scientists to conduct the appropriate long-term (minimum 2 years) safety studies in recognized animal model systems. A thorough and modern assessment of GBH toxicity will encompass potential endocrine disruption, impacts on the gut microbiome, carcinogenicity, and multigenerational effects looking at reproductive capability and frequency of birth defects.”⁵⁹

FDA Announces Testing of Glyphosate Residue in Foods

101. On February 17, 2016, the U.S. Food and Drug Administration (“FDA”) announced that, for the first time in its history, the agency planned to start testing certain foods for glyphosate residues. FDA spokeswoman Lauren Sucher explained: “The agency is now considering assignments

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

for Fiscal Year 2016 to measure glyphosate in soybeans, corn, milk, and eggs, among other potential foods.”⁶⁰

102. In 2014, the U.S. Government Accountability Office (GAO) had severely rebuked the FDA for its failures to both monitor for pesticide residue, including that of glyphosate, and to disclose the limitations of its monitoring and testing efforts to the public.⁶¹ The GAO had cited numerous undisclosed deficiencies in the FDA’s process, specifically highlighting its omission of glyphosate testing.

103. Indeed, in the past, both the FDA and the U.S. Department of Agriculture (USDA) had routinely excluded glyphosate from their testing for the residues of hundreds of other pesticides, on the rationale that it was too expensive and unnecessary to protect public health. Ms. Sucher, the FDA spokeswoman, however, now states that “the agency has developed ‘streamlined methods’ for testing for the weed killer.”⁶²

104. The FDA’s move is significant as the agency possesses enforcement authority and can seek action if pesticide residues exceed enforcement guidelines.⁶³

European Union Vote on Glyphosate Renewal

105. The license for glyphosate in the European Union (EU) was set to expire on June 30, 2016.

⁶⁰ Carey Gillam, *FDA to Start Testing for Glyphosate in Food*, TIME, Feb. 17, 2016, *available at* <http://time.com/4227500/fda-glyphosate-testing/?xid=tcoshare>.

⁶¹ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-15-38, FDA AND USDA SHOULD STRENGTHEN PESTICIDE RESIDUE MONITORING PROGRAMS AND FURTHER DISCLOSE MONITORING LIMITATIONS (2014), *available at* <http://www.gao.gov/products/GAO-15-38>.

⁶² Gillam, *supra* note 46.

⁶³ *Id.*; Pesticide Q&A, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm114958.htm> (last visited April 19, 2016).

106. Without an extension of the license, Monsanto's Roundup[®] and other glyphosate-based herbicides faced a general phase out in EU markets.⁶⁴

107. In the months leading up to the license expiration date, protracted meetings and votes among national experts from the 28 EU Member States failed to produce agreement on an extension.

108. For instance, on March 4, 2016, *The Guardian* reported that France, the Netherlands, and Sweden did not support EFSA's assessment that glyphosate was harmless.⁶⁵ The paper quoted the Swedish environment minister, Åsa Romson, as stating: "We won't take risks with glyphosate and we don't think that the analysis done so far is good enough. We will propose that no decision is taken until further analysis has been done and the EFSA scientists have been more transparent about their considerations."⁶⁶

109. The Netherlands argued that relicensing should be placed on hold until after a separate evaluation of glyphosate's toxicity can be conducted.⁶⁷ Leading up to the vote, Italy joined the other EU states in opposing the license renewal, citing health concerns.⁶⁸

110. On June 6, 2016, Member States voted but failed to reach a qualified majority in favor or against the re-authorization of glyphosate.⁶⁹

⁶⁴ Philip Blenkinsop, Alissa de Carbonnel & Barbara Lewis European, *Commission to extend glyphosate license for 18 months*, REUTERS, June 28, 2016, available at <http://www.reuters.com/article/us-health-eu-glyphosate-idUSKCN0ZE25B>.

⁶⁵ Arthur Neslen, *EU states rebel against plans to relicence weedkiller glyphosate*, THE GUARDIAN, Mar. 4, 2016, available at <http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicence-weedkiller-glyphosate>.

⁶⁶ *Id.*

⁶⁷ Arthur Neslen, *Vote on Controversial weedkiller's European licence postponed*, THE GUARDIAN, Mar. 8, 2016, available at <http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-licence-postponed-glyphosate>.

⁶⁸ *Id.*

⁶⁹ Manon Flausch, *Commission prolongs glyphosate license by 18 months*, EURACTIV, June 29, 2016, available at <http://www.euractiv.com/section/agriculture-food/news/commission-prolongs-glyphosate-licence-by-18-months/>

111. On June 29, 2016, the EU Commission extended the European license for glyphosate for 18 months to allow the European Chemical Agency to rule on the safety of the chemical, which is expected by the end of 2017.⁷⁰

112. On July 11, 2016, the EU voted in favor of a proposal to restrict the conditions of use of glyphosate in the EU, including a ban on common co-formulant POE-tallowamine (POEA) from all glyphosate-based herbicides, including Roundup[®].⁷¹

113. These restrictions, which are non-binding on the EU states, are expected to apply until the European Chemicals Agency issues an opinion on the chemical's safety.⁷²

CAUSES OF ACTION

114. Plaintiff Nicole Soltyka brings each of her causes of action below individually pursuant to the Maryland Wrongful Death Act, Md. Code, Cts. & Jud. Proc. § 3-901, et seq., and as personal representative for the estate of decedent Anthony Soltyka, pursuant to the Maryland Survival Act, Md. Code, Cts. & Jud. Proc. § 6-401.

115. Plaintiff seeks all damages allowed by law pursuant to the Maryland Wrongful Death Act and separately the Maryland Survival Act.

COUNT I **Strict Liability**

116. Each of the preceding paragraphs is incorporated by reference herein.

⁷⁰ Arthur Neslen, *Controversial chemical in Roundup weedkiller escapes immediate ban*, THE GUARDIAN, June 29, 2016, available at <https://www.theguardian.com/business/2016/jun/29/controversial-chemical-roundup-weedkiller-escapes-immediate-ban>

⁷¹ Sarantis Michalopoulos, *EU agrees ban on glyphosate co-formulant*, EURACTIV, July 11, 2016, available at http://www.euractiv.com/section/agriculture-food/news/eu-agrees-ban-on-glyphosate-co-formulant/?nl_ref=16562829

⁷² See Arthur Neslen, *Controversial chemical in Roundup weedkiller escapes immediate ban*, THE GUARDIAN, June 29, 2016.

117. Plaintiff brings this strict liability claim against Defendant for defective manufacture and design.

118. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup[®] products, which are defective and unreasonably dangerous to consumers, users, and other persons coming into contact with them, including Plaintiff, thereby placing Roundup[®] products into the stream of commerce. These actions were under the ultimate control and supervision of Defendant.

119. At all times relevant to this litigation, Defendant designed, researched, developed, formulated, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the Roundup[®] products used by Plaintiff, and/or to which Plaintiff was exposed, as described above.

120. At all times relevant to this litigation, Monsanto's Roundup[®] products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public, and, in particular, to Plaintiff.

121. At all times relevant to this litigation, Monsanto's Roundup[®] products reached the intended consumers, handlers, and users or other persons coming into contact with these products in Missouri and throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

122. Monsanto's Roundup[®] products, as researched, tested, developed, designed, licensed, formulated, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant, were defectively manufactured and designed by Defendant in that when they left the hands of the Defendant's manufacturers and/or suppliers, they were unreasonably dangerous because they were not as safe as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

123. Monsanto's Roundup® products, as researched, tested, developed, designed, licensed, formulated, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant, were defective in manufacture, design and formulation in that when they left the hands of Defendant's manufacturers and/or suppliers, the foreseeable risks associated with these products' reasonably foreseeable uses exceeded the alleged benefits associated with their design and formulation.

124. At all relevant times, Monsanto's Roundup® products created significant risks to the health and safety of consumers and others who were exposed to the products that far outweigh the risks posed by other products on the market used for the same or similar purpose.

125. Therefore, at all relevant times to this litigation, Monsanto's Roundup® products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendant, were defective in design and formulation, in one or more of the following ways:

a. When placed in the stream of commerce, Roundup® products were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would expect.

b. When placed in the stream of commerce, Roundup® products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner.

c. When placed in the stream of commerce, Roundup® products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner.

d. Defendant did not sufficiently test, investigate, or study its Roundup® products and, specifically, the active ingredient glyphosate.

e. Exposure to Roundup® and glyphosate-containing products presents a risk of harmful side effects that outweighs any potential utility stemming from the use of the herbicide.

f. Defendant knew or should have known at the time of marketing its Roundup® products that exposure to Roundup® and specifically, its active ingredient glyphosate, could result in cancer and other severe illnesses and injuries.

g. Defendant did not conduct adequate post-marketing surveillance of its Roundup® products.

h. Defendant could have employed safer alternative designs and formulations.

126. At all times relevant to this litigation, decedent used and/or was exposed to Roundup[®] products in an intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

127. Plaintiff could not have reasonably discovered the defects and risks associated with Roundup[®] or glyphosate-containing products before or at the time of exposure.

128. The harm caused by Roundup[®] products far outweighed their benefit, rendering Defendant's products dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendant's Roundup[®] products were and are more dangerous than alternative products and Defendant could have designed its Roundup[®] products to make them less dangerous. Indeed, at the time that Defendant designed its Roundup[®] products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

129. Defendant's defective design of Roundup[®] amounts to willful, wanton, and/or reckless conduct by Defendant.

130. As a direct and proximate result of the defective design and manufacture of Roundup[®] products, Plaintiff developed NHL and has been injured catastrophically and has been caused severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic damages.

131. Therefore, as a result of the unreasonably dangerous condition of its Roundup[®] products, Defendant is strictly liable to Plaintiff.

132. The defects in Defendant's Roundup[®] products were substantial and contributing factors in causing Plaintiff's grave injuries, and, but for Defendant's misconduct and omissions, decedent Anthony Soltyka would not have passed away.

133. As a direct and proximate result of Defendant placing the defective Roundup[®] products into the stream of commerce, Plaintiff has suffered and continue to suffer grave injuries, and

she and decedent have endured pain and discomfort, as well as economic hardship, including considerable financial expenses for medical care and treatment.

134. As a direct and proximate result of Defendant's sale and distribution of Roundup®, as aforesaid, Mr. Soltyka suffered serious bodily injury and wrongful death.

135. As a further direct and proximate result of Defendant's sale and distribution of Roundup®, the beneficiaries of Plaintiff has suffered great sorrow and mental anguish, and were deprived of the solace, society, and companionship, as well as comfort, guidance, kindly offices, and advice of Mr. Soltyka.

136. As a further direct and proximate result of Defendant's sale and distribution of Roundup®, the Plaintiff has suffered the reasonably expected loss of the income of the decedent, as well as the reasonably expected services, protection, care, financial support, and assistance of Mr. Soltyka, and have incurred medical, funeral, and other related expenses.

COUNT II
Failure to Warn

137. Each of the preceding paragraphs is incorporated by reference herein.

138. Plaintiff brings this strict liability claim against Defendant for failure to warn.

139. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup® products, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Roundup® and specifically, the active ingredient glyphosate. These actions were under the ultimate control and supervision of Defendant.

140. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its

Roundup® products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and persons responsible for consumers (such as employers), and Defendant therefore had a duty to warn of the risks associated with the reasonably foreseeable uses (and misuses) of Roundup® and glyphosate-containing products and a duty to instruct on the proper, safe use of these products.

141. At all times relevant to this litigation, Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and take such steps as necessary to ensure that its Roundup® products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn Plaintiff of the dangers associated with Roundup® use and exposure, and a continuing duty to instruct on the proper, safe use of these products. Defendant, as manufacturer, seller, or distributor of chemical herbicides, is held to the knowledge of an expert in the field.

142. At the time of manufacture, Defendant could have provided warnings or instructions regarding the full and complete risks of Roundup® and glyphosate-containing products because it knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to these products.

143. At all times relevant to this litigation, Defendant failed to investigate, study, test, or promote the safety of its Roundup® products. Defendant also failed to minimize the dangers to users and consumers of its Roundup® products and to those who would foreseeably use or be harmed by Defendant's herbicides, including Plaintiff.

144. Despite the fact that Defendant knew or should have known that Roundup® products posed a grave risk of harm, it failed to warn of the dangerous risks associated with their use and exposure. The dangerous propensities of its products and the carcinogenic characteristics of glyphosate, as described above, were known to Defendant, or scientifically knowable to Defendant

through appropriate research and testing by known methods, at the time it distributed, supplied, or sold the product, and not known to end users and consumers, such as Plaintiff and Plaintiff's employers.

145. Defendant knew or should have known that its Roundup[®] and glyphosate-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendant failed to adequately warn consumers and reasonably foreseeable users of the risks of exposure to these products. Defendant have wrongfully concealed information concerning the dangerous nature of Roundup[®] and its active ingredient glyphosate, and further made false and/or misleading statements concerning the safety of Roundup[®] and glyphosate.

146. At all times relevant to this litigation, Defendant's Roundup[®] products reached the intended consumers, handlers, and users or other persons coming into contact with these products throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

147. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendant's Roundup[®] products in their intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

148. Plaintiff could not have reasonably discovered the defects and risks associated with Roundup[®] or glyphosate-containing products before or at the time of Plaintiff's exposure. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendant.

149. Defendant knew or should have known that the minimal warnings disseminated with its Roundup[®] products were inadequate, but it failed to communicate adequate information on the dangers and safe use/exposure and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses, including agricultural and horticultural applications.

150. The information that Defendant did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled agricultural workers, horticultural workers and/or at-home users such as Plaintiff to utilize the products safely and with adequate protection. Instead, Defendant disseminated information that was inaccurate, false, and misleading and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries associated with use of and/or exposure to Roundup[®] and glyphosate; continued to aggressively promote the efficacy of its products, even after it knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of exposure to Roundup[®] and glyphosate.

151. To this day, Defendant has failed to adequately and accurately warn of the true risks of Plaintiff's injuries and death caused by the use of and exposure to Roundup[®] and its active ingredient glyphosate, a probable carcinogen.

152. As a result of their inadequate warnings, Defendant's Roundup[®] products were defective and unreasonably dangerous when they left the possession and/or control of Defendant, were distributed by Defendant, and used by Anthony Soltyka.

153. Defendant is liable to Plaintiff for injuries caused by its failure and decedent's wrongful death, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of its Roundup[®] products and the risks associated with the use of or exposure to Roundup[®] and glyphosate.

154. The defects in Defendant's Roundup[®] products were substantial and contributing factors in causing Plaintiff's injuries, and, but for Defendant's misconduct and omissions, Plaintiff would not have sustained injuries including Mr. Soltyka's wrongful death.

155. Had Defendant provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Roundup® products, Plaintiff could have avoided the risk of developing injuries as alleged herein and Plaintiff could have obtained alternative herbicides.

156. As a direct and proximate result of Defendant placing its defective Roundup® products into the stream of commerce and failing to warn Plaintiff of the increased risk of NHL associated with the use of and/or exposure to Roundup® products as described herein, Plaintiff has developed NHL and has been injured catastrophically and has been caused severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic damages, including for medical care and treatment. Plaintiff will continue to incur these expenses in the future.

157. As a direct and proximate result of Defendant's failure to warn, as aforesaid, Mr. Soltyka suffered serious bodily injury and wrongful death.

158. As a further direct and proximate result of Defendant's failure to warn, Plaintiff was caused to suffer great sorrow and mental anguish, and were deprived of the solace, society, and companionship, as well as comfort, guidance, kindly offices, and advice of Mr. Soltyka.

159. As a further direct and proximate result of Defendant's failure to warn, Plaintiff has suffered the reasonably expected loss of the income of the decedent, as well as the reasonably expected services, protection, care, financial support, and assistance of Mr. Soltyka, and have incurred medical, funeral, and other related expenses.

COUNT III **Negligence**

160. Each of the preceding paragraphs is incorporated by reference herein.

161. At all relevant times, Defendant breached its duties to Plaintiff and was otherwise negligent in marketing, designing, manufacturing, producing, supplying, inspecting, testing, selling and/or distributing Roundup® products.

162. Defendant, directly or indirectly, caused Roundup® products to be purchased and/or used by Plaintiff.

163. At all times relevant to this litigation, Defendant had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Roundup® products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers, users, and other persons coming into contact with the product.

164. At all times relevant to this litigation, Defendant had a duty to exercise reasonable care in the marketing, advertisement, and sale of its Roundup® products. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Roundup® and appropriate, complete, and accurate warnings concerning the potential adverse effects of exposure to Roundup® and, in particular, its active ingredient glyphosate.

165. At all times relevant to this litigation, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Roundup® and specifically, the carcinogenic properties of the chemical glyphosate.

166. Accordingly, at all times relevant to this litigation, Defendant knew or, in the exercise of reasonable care, should have known that use of or exposure to its Roundup® products could cause Plaintiff's injuries and wrongful death and thus created a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

167. Defendant knew or, in the exercise of reasonable care, should have known that Roundup® is more toxic than glyphosate alone and that safety studies on Roundup®, Roundup®'s adjuvants and "inert" ingredients, and/or the surfactant POEA were necessary to protect Plaintiff from Roundup®.

168. Defendant knew or, in the exercise of reasonable care, should have known that tests limited to Roundup®'s active ingredient glyphosate were insufficient to prove the safety of Roundup®.

169. Defendant also knew or, in the exercise of reasonable care, should have known that users and consumers of Roundup® were unaware of the risks and the magnitude of the risks associated with the use of and/or exposure to Roundup® and glyphosate-containing products.

170. As such, Defendant each breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of its Roundup® products, in that Defendant manufactured and produced defective herbicides containing the chemical glyphosate, knew or had reason to know of the defects inherent in its products, knew or had reason to know that a user's or consumer's exposure to the products created a significant risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of these risks and injuries.

171. Defendant failed to appropriately and adequately test Roundup®, Roundup®'s adjuvants and "inert" ingredients, and/or the surfactant POEA to protect Plaintiff from Roundup®.

172. Despite its ability and means to investigate, study, and test its products and to provide adequate warnings, Defendant failed to do so.

173. Defendant's negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing its Roundup® products without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Roundup® while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of exposure to glyphosate, and, consequently, the risk of serious harm associated with human use of and exposure to Roundup®;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Roundup® products and glyphosate-containing products were safe for their intended use in agriculture, horticulture, and at-home use;

d. Failing to undertake sufficient studies and conduct necessary tests to determine the safety of "inert" ingredients and/or adjuvants contained within

Roundup[®], and the propensity of these ingredients to render Roundup[®] toxic, increase the toxicity of Roundup[®], whether these ingredients are carcinogenic, magnify the carcinogenic properties of Roundup[®], and whether or not “inert” ingredients and/or adjuvants were safe for use;

e. Failing to use reasonable and prudent care in the design, research, manufacture, formulation, and development of Roundup[®] products so as to avoid the risk of serious harm associated with the prevalent use of Roundup[®]/glyphosate as an herbicide;

f. Failing to design and manufacture Roundup[®] products so as to ensure they were at least as safe and effective as other herbicides on the market;

g. Failing to provide adequate instructions, guidelines, and safety precautions to those persons who Defendant could reasonably foresee would use and/or be exposed to its Roundup[®] products;

h. Failing to disclose to Plaintiff, users, consumers, and the general public that the use of and exposure to Roundup[®] presented severe risks of cancer and other grave illnesses;

i. Failing to warn Plaintiff, users, consumers, and the general public that the product’s risk of harm was unreasonable and that there were safer and effective alternative herbicides available to Plaintiff and other users or consumers;

j. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Roundup[®] and glyphosate-containing products;

k. Representing that its Roundup[®] products were safe for their intended use when, in fact, Defendant knew or should have known that the products were not safe for their intended use;

l. Declining to make or propose any changes to Roundup[®] products’ labeling or other promotional materials that would alert the consumers and the general public of the risks of Roundup[®] and glyphosate;

m. Advertising, marketing, and recommending the use of Roundup[®] products, while concealing and failing to disclose or warn of the dangers known by Defendant to be associated with or caused by the use of or exposure to Roundup[®] and glyphosate;

n. Continuing to disseminate information to its consumers, which indicate or imply that Defendant’s Roundup[®] products are not unsafe for use in the agricultural, horticultural industries, and/or home use; and

o. Continuing the manufacture and sale of its products with the knowledge that the products were unreasonably unsafe and dangerous.

174. Defendant knew and/or should have known that it was foreseeable that consumers and/or users, such as Plaintiff, would suffer injuries as a result of Defendant’s failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Roundup[®].

175. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Roundup[®] or its active ingredient glyphosate.

176. As a direct and proximate result of Defendant's negligence, Plaintiff developed the injuries, harm, and economic losses that Plaintiff suffered including death.

177. As a proximate result of Defendant's wrongful acts and omissions in placing its defective Roundup[®] products into the stream of commerce without adequate warnings of the hazardous and carcinogenic nature of glyphosate, Plaintiff developed NHL and was injured catastrophically and suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic damages, including significant expenses for medical care and treatment, and death.

178. As a further direct and proximate result of Defendant's negligent acts and omissions, the beneficiaries of Plaintiff suffered great sorrow and mental anguish, and were deprived of the solace, society, and companionship, as well as comfort, guidance, kindly offices, and advice of Mr. Soltyka.

179. As a further direct and proximate result of Defendant's negligent acts and omissions, the beneficiaries of Plaintiff suffered the reasonably expected loss of the income of the decedent, as well as the reasonably expected services, protection, care, financial support, and assistance of Mr. Soltyka, and have incurred medical, funeral, and other related expenses.

COUNT IV
Breach of Implied Warranties

180. Plaintiff incorporates the preceding allegations herein.

181. At all relevant times, Defendant engaged in the business of testing, developing, designing, formulating, manufacturing, marketing, selling, distributing, and promoting its Roundup[®] products, which are defective and unreasonably dangerous to users, consumers and those in proximity to users, including decedent, thereby placing Roundup[®] products into the stream of commerce. These actions were under the ultimate control and supervision of Defendant.

182. Before the time that Plaintiff was exposed to the use of the aforementioned Roundup[®] products, Defendant impliedly warranted to its consumers and users—including Anthony Soltyka—that its Roundup[®] products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as horticultural herbicides.

183. Defendant, however, failed to disclose that Roundup[®] has dangerous propensities when used as intended and that the use of and/or exposure to Roundup[®] and glyphosate-containing products carries an increased risk of developing severe injuries, including Plaintiff's injuries and decedent's wrongful death.

184. Upon information and belief, Plaintiff reasonably relied upon the skill, superior knowledge and judgment of Defendant and upon its implied warranties that the Roundup[®] products were of merchantable quality and fit for their intended purpose or use.

185. The Roundup[®] products were expected to reach and did in fact reach consumers, users and those in proximity to users, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendant.

186. At all relevant times, Defendant was aware that consumers, users, and those in proximity of users of its products, including Plaintiff, would use Roundup[®] products as marketed by Defendant, which is to say that Plaintiff were the foreseeable users of Roundup[®].

187. Defendant intended that its Roundup[®] products be used in the manner in which Plaintiff in fact used or were exposed to them and Defendant impliedly warranted each product to be of merchantable quality, safe, and fit for this use, despite the fact that Roundup[®] was not adequately tested or researched.

188. In reliance upon Defendant's implied warranty, Plaintiff used or was in proximity to the use of Roundup[®] as instructed and labeled and in the foreseeable manner intended, recommended, promoted and marketed by Defendant.

189. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Roundup® or glyphosate.

190. The harm caused by Defendant's Roundup® products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

191. As a direct and proximate result of Defendant's wrongful acts and omissions Plaintiff has suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, has suffered economic loss, including significant expenses for medical care and treatment, and will continue to incur these expenses in the future.

192. As a direct and proximate result of Defendant's breach, as aforesaid, Mr. Soltyka suffered serious bodily injury and wrongful death.

193. As a further direct and proximate result of Defendant's breach, Plaintiff Nicole Soltyka individually was caused to suffer great sorrow and mental anguish, and was deprived of the solace, society, and companionship, as well as comfort, guidance, kindly offices, and advice of her husband.

194. As a further direct and proximate result of Defendant's breach, the beneficiaries of Plaintiff's decedent have suffered the reasonably expected loss of the income of the decedent, as well as the reasonably expected services, protection, care, financial support, and assistance of Mr. Soltyka, and have incurred medical, funeral, and other related expenses.

COUNT V

Violation of the Maryland Consumer Protection Act

195. Each of the preceding paragraphs is incorporated herein.

196. Defendant marketed its Roundup® directly to consumers such as Anthony Soltyka and Nicole Soltyka in an attempt to induce purchase and use Roundup® in lieu of numerous competing products with similar qualities.

197. Defendant engaged in unfair and deceptive trade practices in the sale of Roundup®.

198. As such, Defendant is in violation of the Maryland Consumer Protection Act ("MCPA"), Md. Code Ann., Comm. Law §§ 13-301, *et seq.*, since it is an unfair and deceptive trade practice for any person may to engage in any unfair, abusive, or deceptive trade practice, in the sale of consumer goods.

199. The MCPA defines deceptive trade practices as, *inter alia*, a failure to state a material fact if the failure deceives or tends to deceive.

200. The MCPA does not require knowledge of the falsity or intent to deceive if a material fact does in fact deceive or intend to deceive.

201. Defendant failed to state material facts related to:

- a. The safety of Roundup®
- b. The carcinogenesis of Roundup®
- c. Other material misrepresentations and omissions.

202. As a proximate and direct result of Defendant's unfair and deceptive trade practices in violation of the MCPA, Plaintiff has suffered actual loss, including, but not limited to, medical bills and pain and suffering.

PRAYER FOR RELIEF

203. Plaintiff Nicole Soltyka brings this claim for herself individually pursuant to the Maryland Wrongful Death Act and seeks all damages allowable by law including mental anguish, emotional pain and suffering, loss of society, companionship, comfort, protection, marital care, attention, advice, counsel, training, guidance, and education. Plaintiff further seeks all economic and non-economic compensatory damages authorized by law in excess of \$10,000,000.00.

204. Plaintiff Nicole Soltyka also brings this claim as personal representative of the estate of decedent Anthony Soltyka and seeks all damages allowable by law in excess of \$10,000,000.00. including:

- a. Past and future medical bills
- b. Past conscious pain and suffering
- c. Lost earnings
- d. Lost earning capacity
- e. All other damages allowed by law

205. Plaintiff further seeks reasonable attorneys' fees pursuant to the Maryland Consumer Protection Act.

JURY DEMAND

Plaintiff demands a trial by jury on all issues allowed.

/s/ Jonathan Nace

Jonathan Nace, Esquire

Respectfully submitted,

Nidel & Nace, P.L.L.C.

/s/ Jonathan Nace

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